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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,525

11/01/2005

David Dakin Iorwerth Wright

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08/06/2008

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EXAMINER

GEORGE, KONATA M

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,525	Applicant(s) WRIGHT ET AL.	
	Examiner KONATA M. GEORGE	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,8,9,12,16,18-20,25,27-29,31,64,87 and 88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,8,9,12,16,18-20,25,27-29,31,64,87 and 88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/5/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 4, 5, 8, 9, 12, 16, 18-20, 25, 27-29, 31, 64, 87 and 88 are pending in this application.

Request for Continued Examination (RCE)

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 18, 2008 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 5, 8, 9, 12, 16, 18-20, 27-29, 31, 87 and 88 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-17, 31 and 33-36 of copending application No. 10/522,527. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed to a foam comprising a liquid phase containing at least one sclerosing agent and a gas phase comprising at least one physiologically acceptable gas. The difference between the two is the instant invention contains a viscosity-enhancing agent. The addition of a viscosity enhancing would have been obvious to one of ordinary skill in the art as a means to formulate the foam in a consistency that would achieve the claimed density and half-life of the foam.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The provisional rejection of claims 1, 8, 18-20, 25 and 27 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 10, 11, 12, 14 and 21 of copending application 10/890,267 is being maintained for the reasons stated in the office action dated July 5, 2007.

Claims 1, 8, 18-20, 25 and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7,

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10, 11, 12, 14 and 21 of copending application No. 10/890,267. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed to a foam comprising a liquid phase containing at least one sclerosing agent and a gas phase comprising at least one physiologically acceptable gas. The difference between the two is the instant invention contains a viscosity-enhancing agent. The addition of a viscosity enhancing would have been obvious to one of ordinary skill in the art as a means to formulate the foam in a consistency that would achieve the claimed density and half-life of the foam.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The provisional rejection of claims 1, 8, 9, 18-20, 27, 28 and 31 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-18, 33 and 35-40 of copending application 11/128,265 is being maintained for the reasons stated in the office action dated July 5, 2007.

Claims 1, 8, 9, 18-20, 27, 28 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-18, 33 and 35-40 of copending application No. 11/128,265. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed to a foam comprising a liquid phase containing at

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least one sclerosing agent and a gas phase comprising at least one physiologically acceptable gas. The difference between the two is the instant invention contains a viscosity-enhancing agent. The addition of a viscosity enhancing would have been obvious to one of ordinary skill in the art as a means to formulate the foam in a consistency that would achieve the claimed density and half-life of the foam.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The provisional rejection of claim 64 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 68, 69, 71, 74-76, 80-82, 87, 88, 91-94, 96, 97, 100-102 and 107 of copending application 11/171,293 is being maintained for the reasons stated in the office action dated July 5, 2007.

Claim 64 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 68, 69, 71, 72, 74-76, 80-82, 87, 88, 91-94, 96, 97, 100-102 and 107 of copending application No. 11/171,293. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed to a method of producing a foam comprising passing a mixture of at least one sclerosing agent and at least one physiologically acceptable gas through a passage. The difference between the two is the cross-sectional dimensions of the passages as claimed in the instant invention. The

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determination of the cross-sectional dimensions would have been obvious to one of ordinary skill in the art as a means to formulate the foam in a consistency that would achieve the desired results of the claimed foam.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The provisional rejection of claim 64 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending application 11/225,860 is being maintained for the reasons stated in the office action dated July 5, 2007.

Claim 64 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending application No. 11/225,860. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed to a method of producing a foam comprising passing a mixture of at least one sclerosing agent and at least one physiologically acceptable gas through a passage having a cross-sectional dimension of from 0.1 to 30 microns, a density of between 0.07 g/mL to 0.19 g/mL and a half-life of at least 2 minutes. The difference between the copending applications is the ranges of the cross-sectional passages, density and half-life. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie

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case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed July 18, 2008 have been fully considered but they are not persuasive.

Applicant argues that the above mentioned applications and patent does not disclose the invention as claimed. The examiner disagrees.

Application 10/522,527 discloses in claim 1 a foam comprising a sclerosing agent and a gas phase and at least one physiologically acceptable gas. Claim 6 teaches that the physiologically acceptable gas can be carbon dioxide and claim 7 teaches that the foam has a density of less than 0.25 g/cm and a half life of greater than 100 secs. In looking to the specification for support it is noted in paragraph 0047 that the viscosity is in the range of 2.0 to 10.0 cP, preferably 2.0 to 5.0 cP. It is also taught that the physiologically acceptable gas can be CO₂ is in the range of 90%. Therefore, it is the position of the examiner that 10/522,527 reads on the claimed invention and a terminal disclaimer is needed to overcome this rejection.

Application 10/890,267 discloses in claims 1, 7, 11 and 14 a foam comprising a sclerosant agent, a gas mixture comprising at least 50% oxygen or carbon dioxide having a half-life of at least 2 minutes (i.e. 120 secs.) and a vol/vol of the liquid from 0.25 to

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5%. Although the reference is silent with respect to the viscosity, it is the position of the examiner that this determination would have been obvious to one of ordinary skill in the art. This determination would have been made through routine experimentation to achieve the desired results of the claimed invention. This is in the absence of any clear showing of unexpected results attributable to the specific viscosity of the foam employed by applicant in the instant case. Therefore, it is the position of the examiner that 10/522,527 reads on the claimed invention and a terminal disclaimer is needed to overcome this rejection.

Application 11/128,265 discloses in claim 1 a foam comprising a sclerosing agent and a gas phase and at least one physiologically acceptable gas. Claim 7 teaches that the physiologically acceptable gas can be carbon dioxide and claim 8 teaches that the foam has a density of less than 0.25 g/cm and a half life of greater than 100 secs.

Although the reference is silent with respect to the viscosity, it is the position of the examiner that this determination would have been obvious to one of ordinary skill in the art. This determination would have been made through routine experimentation to achieve the desired results of the claimed invention. This is in the absence of any clear showing of unexpected results attributable to the specific viscosity of the foam employed by applicant in the instant case. Therefore, it is the position of the examiner that 11/128,265 reads on the claimed invention and a terminal disclaimer is needed to overcome this rejection.

Application 11/171,293 (now US 7,357,336) discloses in claim 1 a foam comprising a sclerosing agent and a gas phase which includes oxygen, carbon dioxide

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or a mixture thereof having a density of less than 0.25 g/cm and a half life of greater than 100 secs. Although the reference is silent with respect to the viscosity, it is the position of the examiner that this determination would have been obvious to one of ordinary skill in the art. This determination would have been made through routine experimentation to achieve the desired results of the claimed invention. This is in the absence of any clear showing of unexpected results attributable to the specific viscosity of the foam employed by applicant in the instant case. Therefore, it is the position of the examiner that 11/171,293 reads on the claimed invention and a terminal disclaimer is needed to overcome this rejection.

Application 11/225,860 discloses the invention as claimed in claim 64 of the instant invention (i.e. the cross-sectional dimension, the density and the half life. It is also disclosed that the composition comprises a blood dispersible gas. In looking to the specification for examples of the gas it is noted in paragraph 0038 that the gas can be carbon dioxide in a concentration of from 10% to 90%. Therefore, it is the position of the examiner that 11/225,860 reads on the claimed invention and a terminal disclaimer is needed to overcome this rejection.

Conclusion

Claims 1, 4, 5, 8, 9, 12, 16, 18-20, 25, 27-29, 31, 64, 87 and 88 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Konata M. George/
Primary Examiner, Art Unit 1616